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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,309	04/09/2001	Roger Howard Meek	A0008/7004	3449
22832	7590	11/24/2003	EXAMINER	
KIRKPATRICK & LOCKHART LLP			DESAUTO, MATTHEW F	
75 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109-1808			3763	
DATE MAILED: 11/24/2003				

IS FX

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/720,309	MEEK ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Matthew F DeSanto	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24,26-29,34-38 and 44-46 is/are pending in the application.
  - 4a) Of the above claim(s) 9-15,34,45 and 46 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8,16-24,26-29,35-38 and 44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Newly submitted claims 45, and 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 45 (Group III) deals with the method of making the medical device, and Claim 46 (Group IV) deals with the apparatus for positioning the stemmed plug in a catheter. The reason for the restriction is Group I (previously picked in paper 11) has Claims 1-8, 16-29, 31-33, 35-38, 40, 41, 42, and 43; and are directed to a catheter and not a method of making the catheter or the apparatus to make the catheter. The specifics of the catheter in Group I are not totally disclosed in Group III, and Group IV, therefore warranting a restriction.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45, and 46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 9-15, 30, 34, 39 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 112***

3. The 112 Rejections have been withdrawn because of the amendments made to the claims.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 8,16-24, 26-29 and 44, are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace (USPN 4,018,231).
3. Wallace discloses a medical device with a proximal end and a distal end, an elastomeric bulb at the proximal end for storing fluid, a fluid acceptor, wherein the acceptor is a balloon, and control device, wherein the control device comprises a plug and wherein the plug comprises a stem, a skirt and an annular part. (Figures 1, 2 and entire reference).
4. Claim 1 – 8,16-24, 26-29, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (USPN 4,116,201).
5. Shah discloses a medical device with a proximal end and a distal end, an elastomeric bulb at the proximal end for storing fluid, a fluid acceptor, wherein the acceptor is a balloon, and control device, wherein the control device comprises a plug. (Figure 1, 2, 3, 7, 8, and entire reference).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-8, 16-24, 26-29, 35-38 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace as applied to the claims above, and further in view of Ericson (USPN 3602226).

Wallace discloses the invention except for using a sleeve, which is made of a shrink-wrap material.

Ericson discloses using a sleeve made of a shrink-wrap material to prevent loss of the inflation fluid from the reservoir and to insure adequate inflation of the retaining means by the inflating fluid upon release of said inflating fluid from the reservoir.

(Figures 2-5 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Wallace with Ericson because Ericson disclosed the use of a shrink-wrap material to prevent fluid from escaping the reservoir.

***Response to Arguments***

8. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

*Matthew*  
Matthew DeSanto  
Art unit 3763  
November 17, 2003

*Brian*  
BRIAN L. CASLER  
SUPPLYING PATENT EXAMINER